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# THE UNITED STATES PATENT AND TRADEMARK OFFICE

**Applicants** 

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Application No.

10/056,794

Confirmation No.

1623

Filed

January 24, 2002

For

A METHOD OF REDUCING IMMUNOGENICITY OR TOXICITY

OF AN ANTIBODY OF IgG CLASS (AS AMENDED)

Art Unit

1642

Docket No.

690022.527C2

Date

September 24, 2002

Box Missing Parts Commissioner for Patents Washington, DC 20231

# PRELIMINARY AMENDMENT

# Commissioner:

Please find enclosed a Petition for an Extension of Time and the appropriate fee.

Prior to examination, please amend the above-identified application as follows:

# In the Specification:

Please replace the title with the following rewritten title:

A METHOD OF REDUCING IMMUNOGENICITY OR TOXICITY OF AN ANTIBODY OF IgG CLASS

Please replace section beginning at page 1, line 3, with the following rewritten section:

### CROSS-REFERENCE TO RELATED APPLICATIONS

i.

This application is a continuation of U.S. Patent Application No. 08/871,488, filed on June 9, 1997, which issued as U.S. Patent No. 6,358,710; which application is a continuation-in-part of U.S. Patent Application No. 08/660,362, filed on June 7, 1996 and abandoned; all of which applications are incorporated herewith in their entirety.

Please amend paragraph beginning at line 6 of page 48 to read as follows:

Essentially, the cDNA sequence encoding the variable regions of NR-LU-13 antibody (hybridoma producing the antibody was deposited with American Type Culture Collection (10801 University Blvd., Manassas, VA 20110) as ATCC Accession No. SD3273, converted to ATCC Accession No. CRL-12360 were cloned and sequenced by known methods. The cDNA sequences of the cloned light and heavy sequence of NR-LU-13 are contained in Figure 2. Using these sequences, the amino acid sequence of the Fv region of NR-LU-13 which includes the entire variable light and variable heavy regions was elucidated.

Please amend paragraph beginning at line 12 of page 56 to read as follows:

The highest producing clone was selected (C2-451C4-100nM HP-2μM HP-161E12-50μM) and subjected to 2 rounds of limiting dilution cloning in 96-well plates in IMDM containing 10% dFBS and 50 μM Methotrexate before cell banking. The final clone was designated C2-451C4-100nM HP-2μM HP-161E12-50μM-12G4-3E7 (hybridoma producing the antibody was deposited with American Type Culture Collection (10801 University Blvd., Manassas, VA 20110) as ATCC Accession No. SD3273, converted to ATCC Accession No. CRL-12360.

In the Claims:

Please cancel claims 1-10, 15 and 17-50 without prejudice.

Please amend claim 16 to read as follows:

16. (Amended) The method of claim 11 or 12 wherein said nucleic acids have been mutated to prevent N-linked glycosylation.

Please add new claims 51 and 52 as follows:

- 51. (New) The method of claim 13 wherein said nucleic acids have been mutated to prevent N-linked glycosylation.
- 52. (New) The method of claim 14 wherein said nucleic acids have been mutated to prevent N-linked glycosylation.

# **REMARKS**

The specification has been amended to update the cross-reference to prior applications. The specification has also been amended to insert American Type Culture Collection (ATCC) information (address and accession number). Claims 1-10, 15 and 17-50 have been cancelled without prejudice. Claim 16 has been amended, and new claims 51 and 52 based on claim 16 have been added, to correct improper multiple dependencies. No new matter has been added. Therefore, claims 11-14, 16 and 51-52 are now presented for examination. The Title of the subject application has been amended to better reflect the subject matter of the now pending claims.

Favorable consideration on the merits is respectfully requested. If the Examiner has any specific questions relating to this application, he or she is respectfully requested to contact the undersigned.

Attached hereto is a marked-up version of the changes made to the specification and claims by the current amendment. The attached page is captioned "Version With Markings to Show Changes Made."

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PATENT TRADEMARK OFFICE

Respectfully submitted,
Seed Intellectual Property Law Group PLLC

Richard G. Sharkey, Ph.D.

Registration No. 32,629

# VERSION WITH MARKINGS TO SHOW CHANGES MADE

In the Specification:

The title has been replaced as follows:

HUMANIZED ANTIBODIES THAT BIND TO THE ANTIGEN BOUND BY ANTIBODY NR-LU-13 AND THEIR USE IN PRETARGETING METHODS

A METHOD OF REDUCING IMMUNOGENICITY OR TOXICITY OF AN ANTIBODY OF IgG CLASS

Section beginning at page 1, line 3, has been replaced with the following rewritten section:

# **CROSS-REFERENCE TO RELATED APPLICATIONS**

This application is a continuation of U.S. Patent Application No. 08/871,488, filed on June 9, 1997, which issued as U.S. Patent No. 6,358,710; which application is a continuation-in-part of U.S. Patent Application No. 08/660,362, filed on June 7, 1996 and abandoned; all of which applications are incorporated herewith in their entirety.

Paragraph beginning at line 6 of page 48 has been amended as follows:

Essentially, the cDNA sequence encoding the variable regions of NR-LU-13 antibody (hybridoma producing the antibody was deposited with American Type Culture Collection (10801 University Blvd., Manassas, VA 20110) as ATCC Accession No. SD3273, converted to ATCC Accession No. CRL-12360 were cloned and sequenced by known methods. The cDNA sequences of the cloned light and heavy sequence of NR-LU-13 are contained in Figure 2. Using these sequences, the amino acid sequence of the Fv region of NR-LU-13 which includes the entire variable light and variable heavy regions was elucidated.

Paragraph beginning at line 12 of page 56 has been amended as follows:

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## In the Claims:

Claims 1-10, 15 and 17-50 have been cancelled without prejudice.

Claim 16 has been amended to read as follows:

16. (Amended) The method of any one of claims 11, 12, 13, 14 or 15 claim 11 or 12 wherein said nucleic acids have been mutated to prevent N-linked glycosylation.

Claims 51 and 52 have been added as follows:

- 51. (New) The method of claim 13 wherein said nucleic acids have been mutated to prevent N-linked glycosylation.
- 52. (New) The method of claim 14 wherein said nucleic acids have been mutated to prevent N-linked glycosylation.

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